

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Feder *et al.*

Serial No.: To be assigned

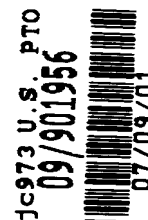
Group Art Unit: 1653

Filed: herewith

Examiner: Gupta, A.

For: PEPTIDES AND PEPTIDE ANALOGUES  
DESIGNED FROM HFE PROTEIN AND THEIR  
USES IN THE TREATMENT OF IRON OVE

Attorney Docket No.: 8907-091-999



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of :

- ☐ Each U.S. patent application publication and U.S. and foreign patent;
- ☐ Each publication or that portion which caused it to be listed on the PTO-1449;
- ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
- ☐ all other information or portion which caused it to be listed on the PTO-1449.

1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non English language publications.

2. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):

- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☐ Before the mailing of the first Office action on the merits;
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
  - ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(i)(1) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement *(applicable if Item 3a or Item 4 is checked)*

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☒ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

*(Check appropriate Items 6a, 6b and/or 6c)*

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

- 6b. ☒ Copies of publications listed on Form PTO-1449 from prior application Serial No. 09/216,077, filed on December 18, 1998, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. *(Check either Item 7a or 7b)*
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on \_\_\_\_\_. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on \_\_\_\_\_.
- 7b. ☐ This Supplemental Information Disclosure Statement is timely filed within one (1) month of a PTO Notice under 37 C.F.R. §1.97(i).
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- ( Check Item 8a, 8b, or 8c)*
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date July 7, 2001

  
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## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

8907-076-999

APPLICATION NO.

09/216,079

APPLICANT

Feder et al.

FILING DATE

December 18, 1998

GROUP

1654

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AA	Dadone et al., 1982, "Analysis of laboratory expression of the disease by genotype in 18 pedigrees", <i>AM. J. Clin. Pathol.</i> 78:196-207
AB	Edwards et al., 1988, "Prevalence of Hemochromatosis Among 11,065 Presumably Healthy Blood Donors", <i>N. Engl. J. Med.</i> 18:1355-1362
AC	Feder et al., 1998, "The hemochromatosis gene product complexes with the transferrin receptor and lowers its affinity for ligand binding", <i>Proc. Natl. Acad. Sci. U.S.A.</i> 95:1472-1477
AD	Feder et al., 1996, "A novel MHC class I-like gene is mutated in patients with hereditary hemochromatosis", <i>Nature Genetics</i> 13:399-408
AE	Feder et al., 1997, "The hemochromatosis founder mutation in HLA-H disrupts beta2-microglobulin interaction and cell surface expression", <i>J. Biol. Chem.</i> 272: 14025-14028
AF	Gross et al., 1998, "Co-trafficking of HFE, a nonclassical major histocompatibility complex class I protein, with the transferrin receptor implies a role in intracellular iron regulation", <i>J. Biol. Chem.</i> 273:22068-22074
AG	Kosbor et al., 1983, "The production of monoclonal antibodies from human lymphocytes", <i>Immunology Today</i> 4:72
AH	Lebron et al., 1998, "Crystal structure of the hemochromatosis protein HFE and characterization of its interaction with transferrin receptor", <i>Cell</i> 93:111-123
AI	McLaren et al., 1995, "Prevalence of heterozygotes for hemochromatosis in the white population of the United States", <i>Blood</i> 86:2021-2027
AJ	Sampietro et al., 1998, "High prevalence of the His63 Asp HFE mutation in Italian patients with porphyria cutanea tarda", <i>Hepatology</i> 27:181-184
AK	Stagsted et al., 1993, "Amino acid residues essential for biological activity of a peptide derived from a major histocompatibility complex class I antigen", <i>Proc. Natl. Acad. Sci. U.S.A.</i> 90:7686-7690
AL	Stagsted et al., 1990, "Regulation of insulin receptor functions by a peptide derived from a major histocompatibility complex class I antigen", <i>Cell</i> 62:297-307
AM	Van Landeghem et al., 1998, "Interaction between haemochromatosis and transferrin receptor genes in multiple myeloma", <i>Lancet</i> 352:1285-1286
AN	Yaouanq et al., 1997, "Hemochromatosis Cys282Tyr mutation in pyridoxine-responsive sideroblastic anaemia", <i>Lancet</i> 349:1475-1476

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>SUPPLEMENTAL LIST OF REFERENCES CITED BY APPLICANT</b> <i>(Use several sheets if necessary)</i>					ATTY DCKE 8907-0076-999		APPLICATION NO 09/216,099	
					APPLICANT Feder et al.			
					FILING DATE December 18, 1998		GROUP 1653	

1653 U.S. PAT.  
 09/216,099  
 09/21/98

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
AO	5,712,098	01/27/98	Tsuchihashi et al.				

FOREIGN PATENT DOCUMENTS							
DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
AP WO 97/38137	10/16/97	PCT (Mercator Genetics Inc.)			YES	NO	
AQ WO 98/56814	12/17/98	PCT (Progenitor, Inc.)					

OTHER REFERENCES <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		

EXAMINER	DATE CONSIDERED
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